

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Effect of Calcium-vitamin D supplementation on serum lipids levels of 50-75 years old women

#### Protocol summary

##### Summary

In this randomized single-blind study without placebo control, the effect of calcium-vitamin D supplementation on serum lipid levels of 100 women 50-75 years old with cholesterol of 200-239 and triglyceride of 150-199 and LDL of 100-159 and vitamin D level less than 30 ng/mL will be investigated. In case of hyperlipidemia, diabetes, heart disease and thyroid diseases, patients are excluded. First, the patient's BMI and waist circumference are calculated. The patients are given Calcium-vitamin D supplement tablets made by Tehran shimi pharmaceutical manufacturing Co. twice-daily (containing 500 mg calcium and 200 IU vitamin D) before breakfast and before lunch for 6 months. Then, blood lipid levels will be recorded after 3 and 6 months. The patient's weight, height and waist circumference are recorded at the end of 6 months and compared with initial data.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017020532406N1**

Registration date: **2017-03-01, 1395/12/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-03-01, 1395/12/11

##### Registrant information

###### Name

Maryam Javadian Kootenaee

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3334 2334

###### Email address

m.javadian@mubabol.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Calcium-vitamin D supplementation on serum lipids levels of 50-75 years old women

##### Public title

Effect of Calcium-vitamin D supplementation on serum lipids levels of 50-75 years old women

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Not using calcium-vitamin D supplementation, normal thyroid hormone levels, satisfaction for participating in study. Exclusion criteria: underlying disease such as hyperlipidemia, diabetes, heart disease, atorvastatin consumption

##### Age

From **50 years** old to **75 years** old

##### Gender

Female

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical sciences

##### Street address

Babol University of Medical sciences, Ganjafrooz Avenue

##### City

Babol

##### Postal code

#### Approval date

2016-10-31, 1395/08/10

#### Ethics committee reference number

MUBABOL.REC.1395.183

## Health conditions studied

### 1

#### Description of health condition studied

Hyperlipidaemia

#### ICD-10 code

E78.5

#### ICD-10 code description

Hyperlipidaemia, unspecified

## Primary outcomes

### 1

#### Description

HDL

#### Timepoint

Baseline

#### Method of measurement

mg/dL

### 2

#### Description

LDL

#### Timepoint

Baseline

#### Method of measurement

mg/dL

### 3

#### Description

TG

#### Timepoint

Baseline

#### Method of measurement

mg/dL

### 4

#### Description

25 Hydroxy vitamin D

#### Timepoint

Baseline

#### Method of measurement

ng/mL

### 5

#### Description

BMI

#### Timepoint

Baseline

#### Method of measurement

kg/m<sup>2</sup>

### 6

#### Description

waist circumference

#### Timepoint

Baseline

#### Method of measurement

cm

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The patients are given Calcium-vitamin D supplement tablets made by Tehran shimi pharmaceutical manufacturing Co. twice-daily (containing 500 mg calcium and 200 IU vitamin D) before breakfast and before lunch for 6 months

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Obstetrics Clinic of Ayatollah Rouhani Hospital of Babol

**Full name of responsible person**

Maryam Javadian, MD

**Street address**

Ayatollah Rouhani Hospital, Ganjafroz avenue

**City**

Babol

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

**Full name of responsible person**

Ali Akbar Moghadamnia, MD

**Street address**

Vice Chancellor for Research and Technology, Babol University of Medical sciences, Gangafroz Avenue

**City**

Babol

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Maryam Javadian, MD

**Position**

Obstetrician

**Other areas of specialty/work****Street address**

Babol University of Medical sciences, Gangafroz

Avenue

**City**

Babol

**Postal code****Phone**

+98 11 2229 4718

**Fax****Email**

m.javadian@mubabol.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Babol University of Medical sciences

**Full name of responsible person**

Shahla Yazdani, MD

**Position**

Obstetrician

**Other areas of specialty/work****Street address**

Babol University of Medical sciences, Gangafroz Avenue

**City**

Babol

**Postal code****Phone**

+98 11 2229 4718

**Fax****Email**

shahla\_yazdani\_1348@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Roya Gharoei, MD

**Position**

Resident of Obstetrics & Gynecology

**Other areas of specialty/work****Street address**

Babol University of Medical sciences, Gangafroz Avenue

**City**

Babol

**Postal code****Phone**

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**Fax****Email****Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*